

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To: ERIC B. MEYERTONS
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Date of Mailing
(day/month/year) **06 SEP 2001**

| | | | |
|--|---|---|--|
| Applicant's or agent's file reference 5259-03701 | | REPLY DUE within TWO months from the above date of mailing | |
| International application No. PCT/US01/00724 | International filing date (day/month/year) 08 JANUARY 2001 | Priority date (day/month/year) 06 JANUARY 2000 | |
| International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/56 and US Cl.: 606/61 | | | |
| Applicant SPINAL CONCEPTS, INC. | | | |

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

*** If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 06 MAY 2002

Docketed
SEP 12 2001

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|--|--|
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer PEDRO PHILOGENE <i>Diane Smith</i> |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-2252 |

I. Basis of the opinion

1. With regard to the elements of the international application:*

☒ the international application as originally filed☒ the description:

pages 1-15

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of☒ the claims:

pages 16-30

pages NONE

pages NONE

pages NONE

, as originally filed
, as amended (together with any statement) under Article 19
, filed with the demand
, filed with the letter of☒ the drawings:

pages 1-11

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of☒ the sequence listing part of the description:

pages NONE

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages none☒ the claims, Nos. none☒ the drawings, sheets/fig none5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

WRITTEN OPINION

International application No.

PCT/US01/00724

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

| | | | |
|-------------------------------|--------|--------------------------------------|-----|
| Novelty (N) | Claims | <u>5-31,36,58,61-117</u> | YES |
| | Claims | <u>1-4,32-35,37-57,59,60,118-131</u> | NO |
| Inventive Step (IS) | Claims | <u>5-31,61-117</u> | YES |
| | Claims | <u>1-4,32-60,118-131</u> | NO |
| Industrial Applicability (IA) | Claims | <u>1-131</u> | YES |
| | Claims | <u>NONE</u> | NO |

2. citations and explanations

Claims 1-4,32-35,37-57,59,60,118-131 lack novelty under PCT Article 33(2) as being anticipated by Bono (5,954,722).

With respect to claims 1,131 Bono discloses a bone plate system (10) comprising a plate (12) configured to stabilize a bone structure (11) a hole (14) passing through the plate; a ring (16) positionable within the hole and fastener (18) positionable through the ring (16), the fastener configured to couple the plate to a bone; wherein a portion of the ring engages a groove in the fastener during use to secure the fastener to the ring; as best seen in figure 6.

With respect to claims 2-4, Bono discloses all the limitations, as set forth.

With respect to claim 32, Bono discloses a bone plate system (10) comprising a plate (12) a hole (14) through the plate, the hole extending from a top of the plate to a bottom of the plate, and wherein the a portion of the plate forms a wall of the hole; as set forth in column 2, lines 1-23, a fastener (18) for coupling the plate to a bone, the fastener comprising a head and a shank (FIG.5); and ring (16) for coupling the fastener to the plate, the ring being positionable within the hole between the plate and the fastener, the ring comprising an outer surface an inner surface and a ridge on a portion of the inner surface; as best seen Fig.5, wherein the ridge on the ring is configured to couple with the head to secure the fastener to the ring during use; as best seen in figure 5.

With respect to claims 33-35,37-57,59, 60, Bono discloses all the limitations, as set forth.

With respect to claims 118-130, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

Claims 36,58 lack an inventive step under PCT Article 33(3) as being obvious over Bono (5,954,722) in view of Schlapfer et al. (5,501,684).

With respect to claim 36, it is noted that Bono did not teach of a ring with a plurality of notches in the ring; as claimed by applicant. However, in a similar art, Schlapfer et (Continued on Supplemental Sheet.)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

al evidences the use of a ring with notches for form-locking and force-locking the head of the screw.

Therefore, given the teaching of Schlapfer et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate notches in the ring of Bono to form-locking and force-locking the head of the screw.

With respect to claim 58, Schlapfer et al disclose device wherein the fastener shank and the additional fastener shank extend from the bottom of the plate in diverging directions relative to each other; as best seen in Fig.5..

Claims 5-31,61-117 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a bone plate system where a ring comprising a finger extending from the projection substantially parallel to the base, the finger configured to secured the head in the ring during use. also, comprising a locking mechanism comprising a top and a plurality of elongated members extending from the top the locking mechanism configured to insert in the opening of the head with a portion of the elongated members extendable through the apertures in the head of the fastener during use.

----- NEW CITATIONS -----

NONE